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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,628	03/16/2007	Carsten Andersen	12684.0020FPWO	9476
23552 7590 01/26/2011 MERCHANT & GOULD PC P.O. BOX 2903 MINNEAPOLIS, MN 55402-0903				
EXAMINER				
SUTTON, DARRYL C				
ART UNIT		PAPER NUMBER		
1612				
MAIL DATE		DELIVERY MODE		
01/26/2011		PAPER		

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

**Application No.**

10/581,628

**Applicant(s)**

ANDERSEN, CARSTEN

**Examiner**

DARRYL C. SUTTON

**Art Unit**

1612

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 October 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☒ Claim(s) 1, 23 and 24 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-940)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

This Office Action is in response to the amendment filed 10/12/2010. New claims 23 and 24 have been added.

Applicant's arguments filed 10/12/2010 have been fully considered. Rejections and/or objections not reiterated from previous Office Actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 2 and 22-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where values can vary depending on the basis for their determination, the claimed subject matter may be indefinite. See Honeywell Intl. v. Intl. Trade Commn., 341 F.3d 1332, 1340 (Fed. Cir. 2003). (Holding that, where a claimed value varies with its method of measurement and several alternative methods of measurement are

available, the value is indefinite when the claim fails to concurrently recite the method of measurement used to obtain it).

Here, the release rate recited by instant claim 1 is incomplete insofar as it does not specify the frame of reference used to measure it, e.g., the USP test method used to measure the release rate. Without knowing these parameters, the metes and bounds of the claimed subject matter are not reasonably clear.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-22 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Walling (US 6,586,449) in view of Ferno et al. (US 3,845,217) and the rejection is applicable to new claims 23 and 24.

Applicant argues that a nicotine delivery product which has the same nicotine loading as the compositions disclosed in Walling, but a nicotine release rate of at least 80% is unexpected and surprising. Applicant points the Examiner to Table A for proof of the alleged of unexpected results.

The data in Table A is not considered probative since the method of measuring the release rate is not specified, making verification of applicant's allegations of unexpected results uncertain. Further, Table A contains data for July 2009 testing of A and B which exhibit release rates of 81.7 and 80.2 respectively, and provides a set of data for September 2010 testing which exhibits a release rate of 78.6, but provides no explanation of what any of this data represents. Applicant has not identified any specific formulation which corresponds to the data, i.e. components, amounts or methods of production. Accordingly, the Examiner is unable to reasonably assess the data so as to come to a definite conclusion of whether the results are unexpected or not.

Applicant argues that Walling discloses that it is necessary to combine the polyol with the cation exchange resin before admixture with nicotine, and therefore specifically teaches away from changing the order of the process steps in Walling. Applicant argues that the Examiner alleges that it would have been obvious to change the order of process steps in Walling as Ferno discloses that the release rate of nicotine can be varied by varying the amount of nicotine bound to the cation exchange resin.

The Examiner disagrees.

The Examiner cited MPEP 2144.04, IV, C. as motivation for changing the order of steps. The Examiner used the rationale of Ferno as an alternate motivation. MPEP 2144.04, IV, C states that "selection of any order of performing process steps is *prima facie* obvious in the absence of new or unexpected results." As discussed *supra*, the Examiner is unable to determine whether the results are unexpected; and accordingly, *prima facie* obviousness has been established.

### ***Double Patenting***

Claims 1-22 stand provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim2, 3, 6, 10-15 and 19-22 of copending Application No. 10/921199.

Applicant requests that the rejection be held in abeyance until allowable subject matter is indicated.

This rejection is maintained since applicant does not argue the merits of the rejection; and neither allowable subject matter has been indicated, nor has a terminal disclaimer been filed.

No claims are allowed.

### ***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within

TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Darryl C. Sutton whose telephone number is (571)270-3286. The examiner can normally be reached on M-Th from 7:30AM to 5:00PM EST or on Fr from 7:30AM to 4:00PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass, can be reached at (571)272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

/Darryl C Sutton/

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Examiner, Art Unit 1612

/Frederick Krass/

Supervisory Patent Examiner, Art Unit 1612